Extramural Official Duties and Conflicts of Interest

CASE STUDIES

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CASE STUDY # 1: An extramural scientist with significant intramural responsibilities

Dr. Jones is a senior member of the extramural staff of the National Institute of Biomedicine (NIB). Her supervisor is the Director of Extramural Activities, who signs her timecard and provides performance ratings. While her responsibilities do not include management of a scientific portfolio, she is involved in meetings in which programs and funding decisions are discussed and she has access to summary statements and grant applications. Because of her scientific expertise and also the nature of her responsibilities, she provides information in these meetings, but does not get involved in recommendations for funding. The "firewall" that was established when Dr. Jones was hired was that she would have no involvement in decisions regarding funding or general program management.

Dr. Jones also has an active intramural research program with a number of collaborations. She has a separate operating budget for this activity from the NIB intramural program and she reports secondarily to an intramural Lab Chief for this part of her job. Dr. Jones publishes widely and is now often invited to present her work at national and international meetings and at research institutions. Many of the research institutions and programs at which she is invited to speak are also supported through the extramural programs of the NIB. Because of limited travel dollars available to her through her laboratory budget, she requests approval of sponsored travel, which is reviewed by the Lab Chief.

Is the firewall that was established at the time of hiring Dr. Jones sufficient to protect her and the NIB from conflict of interest and the perception of unfair advantage by virtue of having knowledge of the research plans of her colleagues and potential competitors?

Perhaps the most important aspect of managing this potential conflict is education of Dr. Jones in the issues at the outset to insure a clear understanding of where they lie and why. A variation of the conflict of interest/confidentiality agreement used for peer reviewers might be appropriate and would document the issues and the fact that Dr. Jones is aware of them This is a complex situation, since Dr. Jones, officially an extramural scientist administrator, is not just working in someone's intramural laboratory, but in fact has one of her own with intramural staff (technicians, post-docs) reporting to her. She needs access to confidential information to perform her extramural responsibilities.

What about her collaborators—is there a conflict when it comes to any discussion about them, and would this be personal or institutional?

It should be made clear to Dr. Jones and others on the staff that she has no role in allocating extramural funds or making administrative decisions after award. It would also be appropriate for her to refrain from any internal discussion related to her collaborators or their work within the extramural staff context, and her supervisor should periodically review these collaborations with Dr. Jones. Under most circumstances, the conflicts would be with the individual collaborators. However there may be some circumstances in which at least a perception of conflict may extend to the collaborator's

laboratory or department, and these should be managed as appropriate with the DEA director.

What about sponsored travel? Since the differentiation between extramural and intramural staff and the practices the NIB has put in place regarding Dr. Jones are not apparent to extramural investigators, and since extramural staff cannot accept sponsored travel from an institution that is or potentially is an applicant/grantee, is Dr. Jones's acceptance of sponsored travel appropriate?.

The sponsored travel is more problematic. As Dr. Jones's official supervisor, the DEA Director should at least initial the request to be aware of the potential for conflict of interest to be able to remind Dr. Jones of the need to limit her presentation strictly to the research from her laboratory and avoid any discussion of grants or applications. Since presentations should have supervisory approval (usually done via the travel order), this documentation would also suffice as that approval. Sponsored travel to grantee institutions should be limited, however, and preferably done with intramural funds as part of her official duties in that arena.

As a final note, different controls would be necessary if the extramural responsibilities were in program or review, in which case such extensive intramural involvement may not be permissible.

CASE Study # 2: Giving Scientific Advice to an IC Director on Extramural Activities

An IC director is interested in a special initiative to encourage the payment of innovative but high-risk applications. He has asked for nominations of innovative applications that have been peer reviewed and approved by Council, but are not within the payline. To sort through the large number of nominations received from IC staff, he has asked the IC's review chief to pull together a selection committee of IC extramural and intramural staff to identify the most innovative applications for his consideration.

Is this permissible?

Given the new specifications for official duty, it is generally permissible for intramural researchers and extramural program, review, and policy staff to serve on this committee.

What protections should be put in place regarding conflicts of interest and confidentiality?

The Review Chief should discuss explicitly the confidential nature of the materials and group discussion, as well as issues pertaining to conflicts of interest. Members should receive, review, and sign the conflict of interest forms used in peer review.

What should the reviewers judge by?

There should be established criteria for judging the merits of the applications, whether or not written critiques are required. These criteria should be available to the nominating staff as well.

Are there any other concerns?
All staff should be clear on who should contact the PI about funding, based on IC determined procedures.

CASE STUDY #3: Scientific Officers on Cooperative Agreements

An extramural Program Director has been significantly involved with a cooperative agreement grant, attending monthly phone conferences and annual meetings of the PIs. The grant includes three primary institutions (with six investigators in close collaboration) plus a network of more than 50 other investigators, who use the core facilities at the primary institutions from time to time. This PD has been designated as the Scientific Officer (SO) for the grant.

A second extramural HSA has been selected to handle the program administrative (PA) responsibilities.

Should the SO recuse herself from programmatic oversight of any application submitted by the six PIs?

The answers depend on the nature of the SO's involvement with the PIs. If she has had substantial scientific involvement and is publishing with the group, she should recuse herself from handling grants from the six PIs and other coauthors on the papers. If the SO's involvement has been more of an advisory role (e.g., as the institute representative to ensure policy is followed), she need not recuse herself from handling their other applications.

Should she recuse herself from any application submitted by the primary institutions?

Even if substantially involved, the SO could serve as program administrator for other applications from the PIs' institutions, unless another conflict exists.

Should the SO recuse herself from any application submitted by the 50 other investigators or their institutions?

Unless there is another conflict, this would not be necessary.

What should the SO's role be for initial or second-level review of the cooperative agreement application?

She can not attend the closed session of study section review for the competing (T2 or 3) applications, nor the Council discussion for that application: the PA must do so. She could attend an open session of the initial review meeting, if one is held. Inasmuch as the SO would not have any involvement with the T1 application, she could attend the initial review meeting.

Case Study #4: Intramural & Extramural Scientific Research Collaboration Within the Same IC

The Chief of the Chemistry intramural laboratory has indicated to an IC extramural Health Scientist Administrator (HSA) that he and his entire group would be delighted if it were possible for the HSA to spend some time in the Chemistry intramural laboratory at any time that is suitable to him. In his invitation, he stated that the HSA's expertise on agents that interact with DNA matches a major interest of his laboratory and it would be mutually beneficial to pool their intellectual resources in this effort. The HSA indicates that collaborating with this intramural group would be directly pertinent to the mission of his IC and that the interaction will enhance his ability to maintain the expertise and skills in his basic research area, which in turn will benefit his responsibilities within the IC as a Review or Program Director. He requests approval to consult with the intramural investigators in this capacity.

The HSA's immediate supervisor has no objections to the HSA's collaborating on this or other research activities with the intramural laboratory in the scope and form described above if it does not impact his performance of his current duties. However, based on the posted descriptions of "outside activities", it is ambiguous to the supervisor whether this activity would comprise an "outside activity" and what steps, if any, are needed to get it cleared.

Is this a permissible activity?

Yes, this is considered an official activity.

Since this is not a part of the HSA's official position or current assigned responsibilities, could participation occur during regular tour of duty hours?

Yes. The HSA could participate during his official duty hours unless his supervisor feels that the employee does not have sufficient time to do his current assignments and the intramural collaboration. He/she may also participate outside his official duty hours.

Would this activity present any level of conflict for the HSA in his position as a review administrator or program director? Are there other issues that must be considered, such as impact of interactions with extramural collaborations with laboratories outside of NIH with the principle intramural laboratory?

Even though the collaboration is considered to be part of the HSA's official duties, conflict of interest must be managed with the investigators in the intramural laboratory and collaborating extramural investigators. The HSA would need to recuse himself from the review or program administration of any grant applications, contract proposals, or awards listing the intramural investigators as key personnel or collaborators. The HSA should not share any confidential or privileged information (e.g., grant applications, contract proposals, progress reports, summary statements) with members of the intramural laboratory that he/she has access to in the regular performance of his duties. The HSA should also not take unfair advantage of any ideas, hypotheses, approaches,

results, conclusions, etc, that he/she gains through his access to confidential materials accessed in the performance of HSA duties.

What steps are needed for approval?

Approval is obtained by the intramural investigator preparing a memo of understanding that invites the HSA to participate in the planned activities and includes any relevant information such as activities, meeting schedules, hours per week, and length of collaboration. The HSA's supervisor would need to approve the activity and sign the memo. The memo would provide documentation for the employee's file.

CASE STUDY # 5: How Collaborative Relationships That Change Over Time Can Impact Conflicts Of Interests – Giving Lectures

Dr. Leber is the HSA who runs the Hepatitis Program in NIDDK. He is asked by Dr. Leiden of Georgetown University to give a lecture on Recent Findings in Hepatitis Research in a graduate course that Dr. Leiden is putting together. Dr. Leber feels that this will not interfere with his NIH duties and would help him maintain his professional standing. When he was a professor before coming to NIH, he had always enjoyed interacting with graduate students. Dr. Leber discusses this with his supervisor and it is agreed that this can be done as an official duty activity. There would be no compensation for this lecture.

Following the lecture, Dr. Leiden and Dr. Leber go to the university cafeteria for lunch. Over lunch they discuss scientific issues of mutual interest. The next week Dr. Leiden contacts Dr. Leber to tell him about the positive feedback he's heard from the students about Dr. Leber's lecture. He mentions that he is going to offer the course during the next semester and invites Dr. Leber back to give the same lecture. After again discussing this with his supervisor, Dr. Leber agrees.

Over the next couple of years, Dr. Leber's lecture becomes a regular part of the course. The post-lecture lunch becomes a tradition as well and Dr. Leber and Dr. Leiden develop a friendship around their mutual scientific interests – they often e-mail each other when they see research articles that they think will interest the other.

One day Dr. Leber sees that Dr. Leiden's new grant application has been referred to his program.

> *Is he in conflict? Should Dr. Leber be considered in conflict with all applications from Georgetown University?*
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> There are no black-and-white answers to these questions. Certainly, Dr. Leber has developed a personal relationship with Dr. Leiden, but it revolves around scientific discussions. Program Directors have such scientific discussions with PIs all of the time. However, this relationship was described as a "friendship" and most PIs are not friends with their Program Director. In addition, the repeated invitations and lectures given by Dr. Leber in Dr. Leiden's course, even though not involving compensation, could be viewed as a standing professional relationship.
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> Dr. Leber should discuss this situation with his supervisor. His supervisor and he may find it useful to include the Director of Extramural Activites in their discussions. It would likely be best if Dr. Leber were recused from handling Dr. Leiden's applications. Dr. Leber and his supervisor should also discuss whether the repeated lectures have developed into an ongoing activity that might place him in conflict with Georgetown University applications. He doesn't have the title of Adjunct Professor, which would immediately convey the appearance of a conflict, but, in fact, he is providing an ongoing

service to Georgetown University that is more than many adjunct faculty members contribute. It appears that this activity would place him in conflict with the university, and his supervisor must consider the impact this conflict has on Dr. Leber's ability to perform his NIH job.

It may be that Dr. Leber will need to end this activity, or perhaps the frequently repeated nature of it.

CASE STUDY #6: IC Directors And Mentorship

Dr.Werner is Drector of the NIH NHLBI institute has an extramural laboratory at the NCI. One of the postdocs, Dr. Chen in his NCI laboratory submits a K99/R00 to NHLBI. As the Director of the Institute he will have final sign off on all K99/R00, will participate in discussions on the program and will make final decisions on how many grants NHLBI should fund and who much money should be dedicated to the program.

How should the application from his postdoc be handled?

As IC director, Dr. Werner is recused with anything to do with Dr. Chen's application. Because the applications are not coming in in response to an RFA, Dr. Werner may have oversight and final sign off on other applications competing with Dr. Chen, but Dr. Werner may not engage in any discussions of Chen's application, nor appear on any paperwork associated with this application.

Who approves documentation for Dr. Chen?

All documentation associated with Dr. Chen should be sent to the DDER for signature or otherwise appropriately handled within the institute.

CAST STUDY # 7: IC Directors With Intramural Laboratories Collaborating With Extramural Organizations.

The Director of the NIH Mental Health Institute, Dr. Mary Cosner, has an intramural laboratory at the Aging Institute. In her intramural capacity, Dr. Cosner is collaborating with scientists at John Hopkins University. Dr. Grannet, an investigator from John Hopkins, who is not a collaborator with Dr. Grannet, submits an application in response to a Mental Health Institute RFA.

Can Dr. Cosner be involved in the review or approval of Dr. Grannet's application?

Dr. Cosner, as Director the Mental Health institute, always is recused from anything to do with John Hopkins University and with any of the scientists with whom she is collaborating. In this particular situation, where a John Hopkins University scientist submits an application to a Mental Health RFA, Dr. Cosner becomes in conflict with the entire RFA and must be recused from anything to do with applications in response to that RFA or activities surrounding the RFA including signing off on any funding decisions.

Who approves documentation in cases where Dr. Cosner is recused?

All signature and actions for grants resulting from this RFA must be sent to the DDER for signature.

What about unsolicited applications John Hopkin's may submit to Mental Health?

If John Hopkins submits an unsolicited proposal to the Mental Health Institute, Dr. Cosner is recused from actions on any John Hopkins applications but otherwise is not in conflict when applications come before her that may have competed in the same review group.

Should Dr. Cosner continue to establish research collaborations with institutions and PIs that are supported by or will submit applications to Mental Health?

Clearly, as an IC Director, Dr. Cosner should carefully consider all collaborations with which she enters in her intramural capacity because of how it may impact her extramural responsibilities. As her collaborations grow more recusals will be necessary which may cause a serious disruption of her extramural responsibilities.

CASE STUDY # 8: Extramural Science Administrators Reviewing Manuscripts

Dr. Hubel is an SRA in NINDS. His scientific area is visual neuroscience, but his present responsibilities are the review of fellowship applications. He receives a request from the editor of The Journal of Neuroscience to review a paper submitted for publication by Dr. Klutz concerning signal transduction in the retina. He thinks that this activity will enhance his professional standing and his supervisor agrees that he can do this as an official duty activity. When he reviews the manuscript it is clear to him that there are fundamental problems in the experimental design and that the work is not of the quality normally expected for that journal. He writes a very negative review. A couple of months later as he is going through the fellowship applications he is to review, he notices that Dr. Auge's application has a supporting letter from his PhD mentor, Dr. Klutz. He discusses the situation with his supervisor.

Should Dr. Hubel have turned down the opportunity to review the manuscript from Dr. Klutz in the first place? Should he recuse himself from the review or can he simply alert the review panel to this potential conflict?

Reviewing scientific manuscripts submitted for publication is an activity that can enhance the professional standing and credibility of HSAs. This should be allowed when it doesn't interfere with the HSA's NIH job. However, occasionally, as in this situation, this activity will result in a conflict that must be managed. Since Dr. Hubel has reviewed Dr. Klutz's recent manuscript he should not handle the review of an application submitted by Dr. Klutz or an application in which Dr. Klutz is involved. It is not sufficient for Dr. Hubel to explain the potential conflict to the review panel. He must alert his supervisor to the conflict/appearance of conflict and recuse himself from handling the review.

If this kind of situation occurs with some frequency, it may affect the supervisor's willingness to approve Dr. Hubel's request to perform manuscript reviews. The supervisor needs to balance Dr. Hubel's professional development, etc. with his ability to perform his job. In this situation it may be difficult, but Dr. Hubel's supervisor should monitor his official duty activities and try to identify potential conflicts as they arise. For example, if Dr. Klutz had submitted an application that normally would go to Dr. Hubel for review, Dr. Hubel's supervisor should have been in a position to have ensured that that application was not referred to Dr. Hubel.

Does reviewing a manuscript always put an SRA in conflict; and if so, for how long?

A number of considerations impact on the seriousness of the conflict or perceived conflict. Note that in the situation described the review of the manuscript occurred recently – had this review occurred several years earlier, there probably would be no need for a recusal. Indeed, Dr. Hubel might not even remember that he reviewed the manuscript. In all similar cases common sense and professional judgment should be

brought to bear. However, it is always useful when an employee notes a potential concern to discuss it with the supervisor.

Would the matter be handled be differently were Dr. Hubel a program officer, rather than an SRA?

Similar considerations come into play were Dr. Hubel a program officer. In fact, since program officers are in a position to make a recommendation regarding funding the potential for an appearance of conflict may even be greater. Finally, there are some extramural scientists who have no responsibilities for specific applications (for example, scientist in policy offices). For these individuals it may be appropriate for the supervisor to issue a blanket waiver allowing them to review manuscripts without seeking separate approval for each, but this will apply to only a small number of extramural scientists.

Case Study # 9: SRAs and Conflicts – Managing a Workshop

An SRA arranges a workshop on analytic methods to familiarize reviewers in her standing committee and interested staff with the uses and limitations of new techniques. She works in conjunction with her Chairperson to invite noted authorities as speakers, and the review group members come in a day early for the workshop. The workshop is a huge success, and with the encouragement of the attendees, the Chairperson and SRA decide to publish the meeting's proceedings.

Is an SRA allowed to hold a workshop?

Such initiative is encouraged, but it requires supervisor approval due to additional costs, as well as the use of the SRA's time.

May an SRA publish with her Chairperson?

If the SRA has made a significant intellectual contribution to the publication and received all clearances for the publication, this activity is encouraged.

Does the workshop create a conflict of interest between the SRA and the invited speakers?

The workshop itself does not create a conflict between the SRA and invited speakers. It is possible to imagine events or discussions that could occur at the workshop that may place a speaker in conflict with the SRA or the committee.

Does the publication create conflicts between the SRA and attendees or among the attendees?

Yes, conflicts are created by the publication, but the level of conflict varies with each role. If the Chair and SRA serve as editors, this becomes an additional conflict over and above their current review relationship. In both cases, the SRA is not able to review the Chairperson's applications, but may review applications from the Chair's department or institution.

If a publication of proceedings results from the workshop, are attendees in conflict with each other?
No.

Case Study # 10 : Public-Private partnerships.

Dr. So-and-So in the NIH IRP is approached by a company whose management has been following his lab's work for several years. The company makes novel reagents and a platform likely to be useful in Dr. S's work, but which are too expensive for him to readily obtain. They offer a partnership with his lab and the NIH, providing reagents and analytical work for free. In return, they ask that he acknowledge their contribution in his papers and that he speak at meetings on their behalf.

Is this a partnership?

Maybe- it depends on to what degree this is merely a transfer of materials and specifically requested analyses vs. a collaborative design process involving initial and ongoing input from the company scientists. Alternatively, it could be structured as an MTA (if it only involves the transfer of reagents); as a CRADA (depending on the intellectual property issues relating to inventions and licensing related to the projects outcomes); or as a gift - if the reagents and/or analyses are donated as (in kind) gifts to the IC. It would be considered a partnership if there were ongoing interactions relating to the design and conduct of the research by both parties. (PPP manual chapter(MC) in development)

Can the arrangement proceed?

Possibly, but only after considering several important issues. Among them:

- Does Dr. S. have any personal financial or interpersonal relationships with the company that are likely to substantially affected by entering into this agreement?
- Will there be a real or apparent conflict of interest as a result of this activity?
- Has he provided equal opportunity and fair access to other companies with similar reagents and capabilities (fair access and inclusivity)?
- Is this science consistent with the program and mandate of his IC and lab?
- Does the conduct of this research represent an NIH program priority?
- Can this science be accomplished better, more cheaply and/or more rapidly by entering into a partnership?
- Does the design of the relationship ensure that no outside parties unduly influence the allocation of government funds?
- Will there be open and public access to the results of the activity?
- Does the donor/partner receive a *quid pro quo* as a result of the donation/partnership?

Can he speak on the company's behalf at scientific meetings?

Dr. S can present his data and results at scientific meetings and in the literature in accordance with his IC's policies regarding presentation and publication. He can acknowledge the contribution of reagents and analysis by the company, but cannot speak

on the company's behalf. Dr. S remains a government scientist and is obligated to present his results fairly and completely. The company cannot seek or obtain rights to influence or limit his presentations, this would represent an unacceptable *quid pro quo*.

Who can make the decision to enter into a partnership?

If this is an MTA or a CRADA, the usual procedures arranged through the IC technology transfer officer need to be completed.

If this is a partnership, the oversight will include the lab chief/branch chief, the SD and the IC Director, who ultimately needs to sign the MOU memorializing the partnership. Guidance from the Office of the General Counsel and the Public-Private Partnership Program should be sought to ensure the agreements are consistent with NIH regulations and policies.

If a gift is made to the institute, the gift regulations would apply to the acceptance of the gift (see xxx:).

What does it depend on?

The decision to enter into a partnership is, first of all, scientifically driven: ensuring that scientific rigor in the interest of the public health is served in this arrangement. Once that has been determined, the details of the arrangement need to explicitly describe the roles and contributions of all the partners, affirm that U.S. laws and regulations and NIH policies will be adhered to, and define the outcomes of the partnership.

What agreements need to be in place?

Partnerships are generally memorialized in Memoranda of Understanding (MOU MC in development) entered into by the parties involved (i.e., the company and the institute). PPP program staff and OGC should be consulted in the development of a partnership and in the drafting and execution of MOUs. If the arrangement is conducted as a CRADA or MTA, then the IC technology transfer office will initiate the process to establish these agreements.

Case 11. **Another Public-Private Partnership**

Dr. Whatshername is the program officer in the keratin program and a nail polish company approaches her to co-fund a program for research and training in fingernail biology. They want to give money to the institute to fund research in very specific projects and to meet with institute officials to help identify candidates for well-paid and highly publicized fellowships. They'd like the fellowship to be identified as the "keratin/company name" fellowships in fingernail biology. How should Dr. W. proceed?

Is this a partnership?

NIH program priorities can be promoted by relationships by outside organizations in a variety of ways. Two possibilities include: 1) when funds are contributed by the outside organization to the NIH as a gift, thereby increasing the funds available to the NIH to make awards, and 2) when independent awards are made by the outside organization to applications submitted to ands reviewed by the NIH, but that have not been funded by the NIH. If the NIH is making the awards, decisions must be made in accordance with institute policies and practices and based on peer review and program priorities. Additional funds received as gifts are awarded and managed just as appropriated funds. Funds awarded by outside organizations, whether based on NIH review results or according to any other criteria, are not NIH awards and follow practices and procedures of the awarding organization. NIH can partner in the awarding of grants by other organizations in many capacities, including in providing advice in the design of the RFA, as reviewers, and as advisers. NIH staff cannot assume fiduciary or financial decision-making or oversight for an outside organization. This applies to both research awards and training awards. (see Guidance for Partnerships for Extramural Funding Initiatives for more information).

Can the arrangement proceed?

Possibly, but only after considering several important issues. Among them:

- Does Dr. W. have any personal financial or interpersonal relationships with the company that are likely to substantially affected by entering into this agreement?
- Will there be a real or apparent conflict of interest as a result of this activity?
- Has she provided equal opportunity and fair access to other companies and/or organizations with similar interests and capabilities (fair access and inclusivity)?
- Is this science consistent with the program and mandate of her IC and program?
- Does the conduct of this research represent an NIH program priority?
- Can this science be accomplished better, more cheaply and/or more rapidly by entering into a partnership?
- Does the design of the relationship ensure that no outside parties unduly influence the allocation of government funds?
- Will there be open and public access to the results of the activity?

- Does the donor/partner receive a *quid pro quo* as a result of the donation/partnership?

Therefore, a donor cannot have the company or organization name attached to the awards if they are NIH awards. The donor can, however, be acknowledged in the RFA and in other documents describing the award as contributing to the NIH's ability to support this award.

Who can make the decision to enter into a partnership?

Extramural program leadership would determine the advisability of entering into this research/training program and develop the necessary agreements and terms. Guidance from the Office of the General Counsel and the Public-Private Partnership Program should be sought to ensure the agreements are consistent with NIH regulations and policies. If a gift is made to the institute, the gift regulations would apply to the acceptance of the gift (see xxx:).

What does it depend on?

The decision to enter into a partnership is, first of all, scientifically driven: ensuring that scientific rigor in the interest of the public health is served in this arrangement. Once that has been determined, the details of the arrangement need to explicitly describe the roles and contributions of all the partners, affirm that U.S. laws and regulations and NIH policies will be adhered to, and define the outcomes of the partnership. If the partnership is limited to a gift to the institute, an MOU may not be needed. If the donor or outside funding agency engages with the institute or program in setting up scientific meetings to examine the scientific basis underlying the program decisions in this subject area, access to the discussion/meeting needs to be open to all appropriate parties (i.e., those with scientific interests in the area and expertise to contribute to the discussion). The science-based decision about whether to proceed will take into consideration of the input from outside parties, including but not limited to that provided by the potential partner. This ensures that the process of government decision-making is not directed by parties who have special or unfair access to the decision-making process.

Can the contributing company or organization receive copies of the applications and/or summary statements from the NIH?

The applicant can convey the application and/or the summary statement to the outside entity, at his or her discretion. The NIH will not, however, transmit the information.

Can representatives from the outside company or organization participate in or observe the review of applications?

To maintain the rigor, confidentiality, and integrity of the peer review process, only individuals who are members of the review panel and NIH staff are permitted to attend the review.

Can the outside organization help the NIH decide which applications to fund and to what level of funding?

The government cannot cede or share the responsibility of deciding how to allocate government funds. Therefore, no outside entity can participate in making initial funding decisions, nor in making yearly decisions regarding continued funding based on progress.

Can he speak on their behalf at scientific meetings?

The RFA can acknowledge that additional support for work in this area (or, specifically, support to extend the funding for this RFA) has been provided by (company name).

What agreements need to be in place?

Partnerships are generally memorialized in Memoranda of Understanding (MOU MC in development) entered into by the parties involved (i.e., the company and the institute). PPP program staff and OGC should be consulted in the development of a partnership and in the drafting and execution of MOUs. If the support is in the form of a gift to the NIH gift fund, see (xxx).